

**K110510 S20 DIGITAL COLOR DOPPLER ULTRASOUND SYSTEM**May 16, 2011  
83 days to decisionK110510 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k110510/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Feb 22, 2011                                      |
| Decision date         | May 16, 2011                                      |
| Days to decision      | 83 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Sonoscape Company Limited</b>        |
| Location       | Dublin, CA, US                          |
| Contact        | Diana Hong                              |
| 510(k) history | 22 submissions · 22 cleared · 2004-2015 |

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